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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,691	09/09/2003	Kevin J. Kayser	GTI-1512	3536

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EXAMINER

KOSSON, ROSANNE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 12/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/658,691

Applicant(s)

KAYSER ET AL.

Examiner

Rosanne Kosson

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20, 21 and 25-31 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20 and 26-30 is/are rejected.
- 7) ☒ Claim(s) 21, 25 and 31 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Sep. 9, 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>Nov. 3, 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The text of those sections of Title 35, U.S. code, not included in this action can be found in a prior office action.

The amendment filed on November 3, 2004 has been received. The amendments to claims 20 and 21 have been entered. Claims 25-31 have been added. Claims 1-19 and 22-24 have been canceled.

Accordingly, claims 20, 21 and 25-31 are examined on the merits herewith.

Claim Objections

Claims 21, 25 and 31 are objected to as being dependent on a rejected base claim. These claims would be allowable if rewritten in independent form including all the limitations of the rejected base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 26-30 are rejected under 35 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described the specification such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, claim 20 recites any biologically pure

culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole. Claim 30 recites any biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole without further degradation of said carbazole. This claim language encompasses a multitude of possible organisms, including organisms neither contemplated nor disclosed by the specification as filed. Applicants have not provided any identification or description for any such biologically pure culture apart from that for Applicants' isolate GTIN11 (ATCC No. BAA-487). Although Applicants have described the procedure by which GTIN11 was isolated, this procedure yielded one carbazole-degrading bacterium, suggesting that this procedure is not widely applicable for isolating other carbazole-degrading microorganisms. Applicants have not provided any other guidance for isolating or detecting carbazole-degrading microorganisms. In view of the great extent of the claimed subject matter, combined with the fact that the specification as filed provides a description of only one carbazole-degrading bacterium, it is clear that at the time of filing the application, Applicants possessed those only the one microorganism actually set forth in the specification. Thus, a holding of failure to meet the written description requirement is required.

Claims 20 and 26-30 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole (claim 20) and a biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole without further degradation of said

carbazole (claim 30), does not reasonably provide enablement for any biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole, or any biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole without further degradation of said carbazole. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. As discussed above with respect to the written description requirement, claim 20 recites any biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole, and claim 30 recites any biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole without further degradation of said carbazole. As also discussed above, this claim language encompasses a multitude of possible organisms that degrade carbazole by cleavage of C-N bonds, including organisms neither contemplated nor disclosed by the specification as filed and for which Applicants have provided no guidance as to their identification or isolation, apart from the procedure that resulted in the isolation of Applicant's *Sphingomonas* GTIN11. In view of the great extent of the claimed subject matter, combined with the fact that the specification as filed provides a description of only a limited amount of guidance (how GTIN11 was isolated), is clear that in order to practice the scope of the claimed subject matter, the artisan of ordinary skill would have expected to have undertaken essentially a trial and error process, particularly with regard to potential sources of microorganisms. Such a process clearly amounts to undue experimentation. Because the specification

Art Unit: 1651

provides only a very limited amount of guidance leading to the isolation of one carbazole-degrading organism, the skilled artisan clearly would have expected to have to experiment unduly to practice the claimed invention. In sum, undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth the claims (In re: Wands, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). A holding of non-enablement is, therefore, clearly required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 30 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as their invention. Claim 30 recites a biologically pure culture comprising an operon that encodes genes that selectively cleave both C-N bonds of carbazole without further degradation of said carbazole. The specification does not define the molecular structure or structures produced by cleavage of the C-N bonds of carbazole without degradation of the molecule or molecules.

The specification states that the carA genes (carAa, carAb, carAc and carAd) convert carbazole to 2-aminobiphenyl-2,3-diol (bottom of p. 21 and top of p. 22) and that carbazole is completely degraded to CO₂ and water (p. 12, lines 17 and 18) or to water-

soluble metabolites (p. 21, line 15). On p. 15, it is further stated that the carbazole degradation pathway does not selectively remove nitrogen from carbazole and that a selective pathway would be preferred, analogous to the *dsz* pathway for removal of sulfur from DBT by *Rhodococcus erythropolis* (lines 13-19).

Thus, it is unclear what product of the operon is meant or detected. Consequently, the metes and bounds of the claims are unclear, and it cannot be determined what Applicants intend to exclude from, or include in, the claim. A holding of indefiniteness is therefore required.

Claim Rejections - 35 USC § 102

Claims 20, 26-28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Kirimura et al., Biosci Biotechnol Biochem 63(9):1563-1568, 1999 and by Nojiri et al., J Bacteriol 183(12):3663-3679, 2001. Kirimura discloses a biologically pure culture of a Sphingomonas (CDH-7) that selectively cleaves both C-N bonds of carbazole as shown in Fig. 1, p. 1565. Cleavage of the first C-N bond opens the heterocyclic ring to produce 2-aminobiphenyl-2,3-diol, and cleavage of the second C-N bond removes the amino group present in 2-aminobiphenyl-2,3-diol. Cleavage of the amino group is detected by measuring an increase in the ammonia produced as the reaction proceeds (see Fig. 2, p. 1565).

Nojiri discloses a biologically pure culture of a Pseudomonas (CA10) that selectively cleaves both C-N bonds of carbazole as shown in Fig. 1, p. 3664. Cleavage of the first C-N bond, by enzymes encoded by the CarA genes, opens the heterocyclic

ring to produce 2-aminobiphenyl-2,3-diol, and cleavage of the second C-N bond removes the amino group present in 2-aminobiphenyl-2,3-diol.

Thus, a holding of anticipation is required.

Regarding Applicants' arguments against the following references, which were applied in the previous Office Action- Sierra (U.S. 3,276,840); Sato et al. (J Bacteriology 179(15):4841-4849, 1997); Outtrup (Outtrup I, U.S. 5,856,167); Outtrup et al. (Outtrup II, U.S. 5,888,797) and Outtrup et al. (Outtrup III, U.S. 5,928,929)- all of Applicants' arguments have been considered to the extent that they apply to the amended claims and prior art cited above. In particular, Applicants note that there are differences in the carbazole degradation pathway between GTIN11 and Pseudomonas CA10. In both organisms, however, the carA genes convert carbazole to 2-aminobiphenyl-2,3-diol by cleaving a first C-N bond in carbazole, and the second C-N bond in the carbazole molecule is cleaved by an enzyme to remove an amino group. To use Applicants' terminology, this enzyme is an amidase. In response to Applicants' argument that the prior art fails to show certain features of Applicants' invention, it is noted that the features upon which applicant relies (i.e., the differences in the two carbazole degradation biochemical pathways of GTIN11 vs. Pseudomonas CA10) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1651

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

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2004-12-08



FRANCISCO PRATS
PRIMARY EXAMINER